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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,841	07/27/2005	Robert Wieder	601-1-134PCTUS	1291
23565 7590 12/11/2007 KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER NATARAJAN, MEERA	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,841	<b>Applicant(s)</b> WIEDER, ROBERT	
	<b>Examiner</b> Meera Natarajan	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-12,47 and 50-59 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,10,11,47,50-52 and 55-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,9,12,53 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/20/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment filed 09/20/2007 is acknowledged and entered into the record. Accordingly, Claims 3, 4, 13, and 49 are cancelled herein without prejudice.
2. Claims 1, 5, 7-12, 47, 50-59 are pending. Claims 7, 8, 10, 11, 47, 50-52, and 55-59 are withdrawn as being drawn to non-elected inventions.
3. Claims 1, 5, 9, 12, 53, and 54 will be examined on the merits.

### ***Claim Rejections Maintained - 35 USC § 102***

4. The rejection of claims 1, 5, 9, 12, 53 and 54 under 35 USC 102(b) as being anticipated by Nista et al. (Int. J. of Cancer 1997) is maintained for the reasons of record. Applicant argues that Nista et al. does not teach nor suggest the claimed method in view of the amendments to the claims. Applicant argues that "Nista et al. do not teach nor suggest a method of disrupting survival signaling from a bone marrow microenvironment to a single breast cancer cell or breast cancer cell micrometastases or a method of inhibiting cellular proliferation or inducing cell death or cellular differentiation of a single breast cancer cell or breast cancer cell micrometastases or for treating a single breast cancer cell or breast cancer cell micrometastases as presently claimed" (see p.11-12 Applicants response filed 09/20/2007). In addition Applicant argues that Nista et al. "relate to cell populations that are at a proliferative density, wherein cell-cell contact occurs and contributes to cellular response. In other words, the cell populations examined were not plated at clonogenic density, but rather were plated at much higher densities (see p. 12 Applicants response filed 09/20/2007).

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

5. The amendments to the claims have not altered the active steps of the claims. The claims are still drawn to a method comprising administering an agent effective in blocking or downregulating expression of the interaction of alpha 5 beta 1 with fibronectin in breast cancer cells. Nista et al. teach that treatment with GRGDSP-containing synthetic peptide, blocks the interaction of alpha 5 beta 1 with fibronectin, causing inhibition of proliferation and apoptosis. Although Nista et al. do not use cell populations plated at clonogenic density, the populations used contain cultures of single breast cancer cells and therefore inherently teach the limitation. In addition, it would be obvious to perform a clonogenic assay using the MCF-7 cells taught by Nista et al. to further evaluate the efficacy of treatment with the GRGDSP-peptide. It is also well known in the art that fibronectin is a major constituent of the bone marrow microenvironment, therefore blocking the interaction of alpha 5 beta 1 with fibronectin in breast cancer cells, would inherently occur in breast cancer cells that metastasize to the bone marrow microenvironment where fibronectin is present. The rejection is maintained because Nista et al. teach each and every limitation of the claims.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in the response filed 09/20/2007.**

***Conclusion***

6. Claims 1, 5, 9, 12, 53 and 54 are rejected.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

Application/Control Number:  
10/521,841  
Art Unit: 1643

Page 5

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER